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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,137	02/15/2002	Browning Jeffrey	08201.0027-00000	2907

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BIOGEN IDEC / FINNEGAN HENDERSON, LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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12/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/077,137	Applicant(s) JEFFREY ET AL.	
	Examiner Patricia A. Duffy	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9-17-08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32, 33, 35, 36, and 38 is/are allowed.
- 6) ☒ Claim(s) 19, 20, 26, 27, 29, 39, 40, 42, 43, 45-47, 49, 50, 52-57 and 59-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are Claims 19, 20, 25-27, 29, 32-33, 35, 36, 38-40, 42, 43, 45-47, 49, 50 and 52-61.

RESPONSE TO AMENDMENT

The response filed 9-17-08 has been entered into the record. Claims 19, 20, 25-27, 29, 32-33, 35, 36, 38-40, 42, 43, 45-47, 49, 50 and 52-61 are pending and under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Maintained

Claims 19, 20, 26, 27, 29, 39, 40, 42, 43, 45, 46, 47, 49, 50, 52, 53, 54, 55, 56, 57, 59, 60 and 61 are rejected under 35 U.S.C. 102(e) as anticipated by Gross et al US 2006/0067933 with priority to provisional Application 60/115,068 filed January 1, 1999 for BCMA compositions of SEQ ID NO:6, fusions) is maintained for reasons made of record in the Office Action mailed 5-14-08.

With respect to the disclosure of the earliest priority document Gross et al '068 describe the polypeptides of the present invention a TACI isoform having only one cysteine-rich pseudo-repeat, TACI per se and a related B cell protein BCMA were found to bind the TNF ligand zTNF4, also known as neutrokin alpha, BAFF, Blys, TALL-1 and THANK would be useful to regulate the activity of ztnf4 (neutrokin alpha) on the activation of B cells (paragraph bridging pages 1-2). The figure demonstrates BCMA alignment and the particular domains of the proteins of the invention as described by Gross et al. The specification of the provisional document teaches the fusions of such proteins to heterologous protein, including heavy chain constant regions of immunoglobulins and further teaches administration *in vivo* (see pages 4-5) and a fragment of the BCMA receptor protein. The specification teaches compositions comprising such at pages 63, 73 and 74. As such, the compositions of the prior art anticipate the instantly claimed compositions.

Applicants' arguments have been carefully considered but are not persuasive. Applicants argue that with respect to the claims, the document of the prior art is (1) not enabling and (2) does not teach solubility in water and the fusions of the prior art would not be soluble in water. With respect to the term "soluble", the claims do not state soluble in water. Further, Applicants assert insolubility in water but provide no evidence thereof, but instead rely upon a review of Goding et al indicating that membrane proteins in general are by definition insoluble in water. This does not address the single membrane spanning region of the prior art protein or the family of TNF receptor proteins to which this receptor belongs most of which have been successfully purified and expressed recombinantly in the full length form. Furthermore, Gross et al characterize Applicants argue that the insoluble fusions of the prior art would not bind BAFF. This is again not persuasive because it is an assertion by counsel unsupported by evidence, and is contradicted by the reference Figure 4, indicating that BCMA-Ig prepared by the general methods of the provisional document comprising the claimed regions is soluble and effective to bind zTNF4 (i.e. the instant BAFF) and inhibit zTNF4 specific proliferation. Applicants argue that the region of the provisional document is longer, this is not persuasive, the claims recite "comprising" and as such read on the fusion of the prior art. Further, "consisting essentially of" language of the claims is interpreted as "open" language as the other residues of the fusion protein do not materially affect its function to bind BAFF as claimed. Applicants argue that the provisional document is not enabling, this is not persuasive because the state of the art with replete with examples of soluble or soluble fusion proteins of the TNF receptor superfamily as acknowledged by the prior art documents of record. The skill of the art in gene and protein expression is very high and one merely would apply the known techniques and exemplification of the provisional document to arrive at the polypeptide. The provisional document is enabling for the its claimed invention and the fusion is soluble and binds BAFF as evidenced by the non-provisional filing. When the reference relied on expressly anticipates or makes obvious all

of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). Priority to Applicants earliest priority document is not granted for reasons made of record.

The rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1645

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisors, Robert Mondesi can be reached at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/

Primary Examiner